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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/705,579 | 11/02/2000 | Brian M. Fendly | P1053R1D1 | 5667 |

7590 09/20/2004

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EXAMINER

YAEN, CHRISTOPHER H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| | 1642 |

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/705,579 | FENDLY, BRIAN M. | |
| | Examiner | Art Unit | |
| | Christopher H Yaen | 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 March 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 42,44,55,63 and 65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 42,44,55,63 and 65 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>6/12/03</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Re: Fendly et al 18 October 1996
Priority Date: 18 October 1996

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. The amendment filed 3/8/2004 is acknowledged and entered into the record. Accordingly, claims 1-41,43,45-54,56-62, and 66-68 are canceled without prejudice.
3. Claims 42,44,55,63, and 65 are pending and examined on the merits.

Information Disclosure Statement

4. The Information Disclosure Statement filed 6/12/2003 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Terminal Disclaimer

5. The terminal disclaimer filed on 3/29/2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 5,720,954 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 42,44,55,63, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hudziak *et al* (US Patent 5,720,954, previously cited) in view of Pauwels *et al* (J. Pharm. Pharmacol. 1995 Oct;47(10):870-875).

a. Hudziak *et al* (US Patent 5,720,954) teach the administration of an anti-HER2 antibody in combination with vinblastine (see col. 6, line 64) for the treatment of carcinoma (i.e. breast, renal, gastric, and salivary – see claim 24). More specifically, Hudziak *et al* teach the administration of a 4D5 antibody (see claim 22, in particular).

b. Hudziak *et al* however fail to teach the combination of the anti-HER2 antibody in combination with vinorelbine.

c. Pauwels *et al* (J. Pharm. Pharmacol. 1995 Oct;47(10):870-875) teach the effects of vinca drugs as anti-cancer agents in general. More specifically, it is taught that vinca alkaloids asserts its affect by the same means or mode of

action (i.e. in the inhibition of cell proliferation, and in the induction of cell in the mitosis phase of the cell cycle – see abstract).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to treat a tumor or cancer comprising the administration of an anti-Her2 antibodies in combination with vinorelbine. One of skill in the art would have been motivated to do so because it was already known and established by Hudziak *et al* that the combination of anti-HER2 antibody and vinblastine was effective, and one of skill in the art would reasonably predict that the substitution of vinblastine with another drug within the same family would also provide the same effect. Further, it was also well established at the time of the invention that vinca alkaloids assert their effects via the same mechanism of action, namely in the inhibition of cell cycle progression or in the inhibition of cell proliferation as evidenced by Pauwels *et al.* There would also be a reasonable expectation of success in doing so because when Pauwels *et al* compared the effects of four different vinca alklooids, little difference or distinction was noted in their study, but rather the class of drugs was compared to as a whole (see abstract in particular). This would indicate that the class of vinca alkaloids would exhibit the same type of result, and one of skill in the art would reasonably expect that the substitution of one for the other would also be as effective.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 3/8/2004.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
August 23, 2004

Gary Nickol
GARY NICKOL
PRIMARY EXAMINER